Paper No. 28

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte ALAN D. SNOW and GERARDO CASTILLO

Appeal No. 2003-0565
Application No. 09/079,829

ON BRIEF

Before SCHEINER, MILLS, and GREEN, Administrative Patent Judges.

MILLS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. §134 from the examiner's final rejection of claims 1-13 and 44-54, which are all of the claims pending in this application.

Claims 1, 3 , 5, 9 and 11 are illustrative of the claims on appeal and read as follows:

1. A pharmaceutical agent for treating an amyloid disease in a patient, wherein the pharmacological agent comprises a therapeutically effective amount of plant matter from a plant of the genus Uncaria.

3. The pharmacological agent of claim 2, wherein the plant matter comprises an extract obtained from Uncaria tomentosa, the extract being derived from the inner bark

or root tissue of Uncaria tomentosa.

5. The pharmacological agent of claim 4 wherein commercially available source of Uncaria tomentosa is selected from the group consisting of pills, tablets, caplets, soft and hard gelatin capsules, lozenges, sachets, cachets, vegicaps, liquid drops, elixers, suspensions, emulsions, solutions, syrups, tea bags, aerosols (as a solid or in a liquid medium), suppositories, sterile injectable solutions, sterile packaged powders, bark bundles or bark powder.

9. The pharmacological agent of claim 1 wherein said amyloid disease for treatment is selected from the group consisting of the amyloid disease associated with Alzheimer's disease, Down's syndrome and hereditary cerebral hemorrhage with amyloidosis of the Dutch type (wherein the specific amyloid is referred to as beta-amyloid protein or Aβ), the amyloid associated with chronic inflammation, malignancy and Familial Mediterranean Fever (wherein the specific amyloid is referred to as AA amyloid or inflammation-associated amyloidosis), the amyloid associated with multiple myeloma and other B-cell dyscrasias (wherein the amyloid is referred to as AL amyloid), the amyloid associated with type II diabetes (wherein the specific amyloid is referred to as amylin or islet amyloid) , the amyloid associated with prion diseases including Creutzfeldt-Jakobt disease, Gerstmann-Straussler syndrome, kuru and animal scrapie (wherein the amyloid is referred to as PrP amyloid), the amyloid associated with long-term hemodialysis and carpal tunnel syndrome (wherein the amyloid is referred to as $beta_2$-microblobulin amyloid), the amyloid associated with senile cardiac amyloid and Familial Amyloidotic Polyneuropathy (wherein the specific amyloid is referred to as thransthyretin or prealbumin), and the amyloid associated with endocrine tumors such as medullary carcinoma of the thyroid (wherein the amyloid is referred to as variants of procalcitonin.

11. The pharmaceutical agent of claim 3, wherein the weight percentage of plant extract in the agent is in the range of from about 70% to about 95%.

The prior art references relied upon by the examiner are:

Keplinger et al. (Keplinger)	4,940,725	July 10, 1990

Stuppner et al. (Stuppner), "HPLC Analysis of the Main Oxindole Alkaloids from Uncaria tomentosa," Chromatographia, Vol. 34, No. 11/12, pp. 597-600 (1992).

Grounds of Rejection

Claims 5, 6, 9, 47 and 50 stand rejected under 35 U.S.C. § 112, second paragraph as indefinite.

Claims 1-10, 12, 13, 44-51, 53 and 54 stand rejected under 35 U.S.C. § 102(b) as anticipated by Keplinger.

Claims 1-6, 9, 10, 12, 13, 44-47, 50, 51, 53 and 54 stand rejected under 35 U.S.C. § 102 as anticipated by Stuppner.

Claims 1-3, 11, 44-46 and 52 stand rejected under 35 U.S.C. § 103 as obvious over Keplinger or Stuppner.

We affirm each of the above rejections for anticipation. We affirm the rejection of claims 1-3 and 44-46 for obviousness over Keplinger or Stuppner. We reverse the rejection of claims 11 and 52 for obviousness over Keplinger or Stuppner.

Claim Grouping

According to appellants claims 1-13 and 44-54 do not stand or fall together, and set forth as proposed in the grouping of claims for each ground of rejection. 37 CFR 1.192(c) (7) states that "[f]or each ground of rejection which appellant contests and which applies to a group of two or more claims, the Board shall select a single claim from the group and shall decide the appeal as to the ground of rejection on the basis of that claim alone unless a statement is included that the claims of the group do not stand or fall together and, in the argument under paragraph (c)(8) of this section,

appellant explains why the claims of the group are believed to be separately patentable. Merely pointing out differences in what the claims cover is not an argument as to why the claims are separately patentable. "

In arguing the merits of the rejections, Appellants present no separate arguments with respect to the individual claims in each group, except for claims 11 and 52. For example, pages 12-13 of the Brief indicate the subject matter that the claims cover but provide no specific argument as to why the claims are separately patentable in view of the prior art. See In re Kaslow, 707 F.2d 1366, 1376, 217 USPQ 1089, 1096 (Fed. Cir. 1983) ("Since the claims are not separately argued, they all stand or fall together."). We treat the claims subject to each rejection separately. Thus, we treat claims 1 and 11 as representative of each rejection before us. In Young, 927 F.2d 588, 590, 18 USPQ2d 1089, 1091 (Fed. Cir. 1991).

DISCUSSION

In reaching our decision in this appeal, we have given consideration to the appellants' specification and claims, to the applied references, and to the respective positions articulated by the appellants and the examiner.

Rather than reiterate the conflicting viewpoints advanced by the examiner and the appellants regarding the noted rejections, we make reference to the examiner's Answer for the examiner's reasoning in support of the rejection, and to the appellants' Brief dated April 12, 2002, for the appellants' arguments thereagainst. As a consequence of our review, we make the determinations which follow.

Background

The claimed invention is directed to a pharmaceutical agent for treating an amyloid disease in a patient, wherein the pharmacological agent comprises a therapeutically effective amount of plant matter from a plant of the genus Uncaria.

More particularly, the specification provides for extracts from the inner bark and root parts of Uncaria tomentosa. Specification, page 6. According to the specification, page 9, the amyloid disease for treatment with the pharmacological agent is selected from the group consisting of the amyloid associated with Alzheimer's disease, Down's syndrome and hereditary cerebral hemorrhage with amyloidosis of the Dutch type, the amyloid associated with chronic inflammation, various forms of malignancy associated with Familial Mediterranean Fever, the amyloid associated with multiple myeloma and other B-cell dyscrasias, the amyloid associated with type II diabetes, the amyloid associated with prion diseases including Creutzfeldt-Jakobt disease, Gerstmann-Straussler syndrome, kuru and animal scrapie, the amyloid associated with long-term hemodialysis and carpal tunnel syndrome, the amyloid associated with senile cardiac amyloid and Familial Amyloidotic Polyneuropathy and the amyloid associated with endocrine tumors such as medullary carcinoma of the thyroid. Specification, page 2. The specification indicates that preferably the U. tomentosa is formulated in a unit dosage form, each dosage containing from about 1 to about 10,000 mg. Specification, page 35. A non-limiting example of an effective dosage is between 10 and 1000 mg/kg

of body weight per day. Specification, page 37.

35 U.S.C. § 112, second paragraph

Claims 5, 6, 9, 47 and 50 stand rejected under 35 U.S.C. § 112, second paragraph as indefinite due to the use of parenthesis in the claims. The examiner argues that the "use of parenthesis is considered indefinite because it cannot be determined when the closed limitation is or is not to be included in the claim." Answer, page 3.

The appellants respond to this rejection, arguing that appellants have "expressly affirmed that all of the parenthetical material in each of these claims is to be included in the respective claim as limitations." Brief, page 6. The appellants also argue that the examiner cited no authority to support the position that the presence of parenthesis in claims is indefinite.

It is well settled, however, that a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in Ex parte Wu, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely

exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of Ex parte Steigewald, 131 USPQ 74 (Bd. App. 1961); Ex parte Hall, 83 USPQ 38 (Bd. App. 1948); and Ex parte Hasche, 86 USPQ 481 (Bd. App. 1949). In the present instance, we find in the case of representative claims 5 and 9 that the use of parenthesis and the language "including" and "such as" in the claims rendering the claims indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. The rejection of claims 5, 6, 9, 47 and 50 under 35 U.S.C. § 112, second paragraph, as indefinite due to the use of parenthesis in the claims is affirmed.

35 U.S.C. § 102(b)

Claims 1-10, 12, 13, 44-51, 53 and 54 stand rejected under 35 U.S.C. § 102(b) as anticipated by Keplinger. Claims 1-6, 9, 10, 12, 13, 44-47, 50, 51, 53 and 54 stand rejected under 35 U.S.C. § 102(b) as anticipated by Stuppner.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros., Inc. v. Union Oil Co., 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). In addition, the language in a claim preamble acts as a claim limitation only when such language serves to "give meaning to a claim and properly define the invention," not when the preamble merely states a purpose or intended use of the

invention. In re Paulsen, 30 F.3d 1475, 1479, 31 USPQ2d 1671, 1673 (Fed. Cir. 1994) (quoting DeGeorge v. Bernier, 768 F.2d 1318, 1322 n.3, 226 USPQ 758, 766 n.3 (Fed. Cir. 1985)).

According to the examiner, Keplinger discloses an oral pharmaceutical product extracted from U. tomentosa. The extract contains oxindole alkaloids and is administered in a pharmaceutical carrier. Answer, pages 3-4. Keplinger indicates at column 3, lines 4-9 that extracts of U. tomentosa can be used as "anti-tumor agents, contraceptives or anti-inflammatory agents."

Stuppner describes the separation of oxindole alkaloids from the root bark of U. tomentosa and indicates that in the last 10 years extracts of the root bark have been used to treat patients with certain types of cancer and viral diseases. Stuppner, page 597, Column 1.

We agree that the examiner has established a prima facie case of anticipation over Keplinger or Stuppner. Each publication describes a pharmaceutical agent which is an extract of a plant of the genus Uncaria and a carrier, meeting each element of claim 1. Keplinger, column 2, lines 20-34 discloses a therapeutically effective amount of an extract of a plant of the genus Uncaria.

The appellants respond to this rejection arguing that the examiner has acknowledged that "Keplinger does not teach administering the *Uncaria tomentosa* extract for treating amyloid diseases as claimed by applicant." Brief, page 7.

However, each of the claims before us is drawn to a pharmaceutical agent and is

not directed to a method of administering a pharmaceutical agent to treat a specific condition, as argued by appellants.

Moreover, it is well settled that the recitation of a new intended use for an old product does not make a claim to that old product patentable. In re Spada, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990) ("The discovery of a new property or use of a previously known composition, even when that property and use are unobvious from prior art, can not impart patentability to claims to the known composition."). A composition claim reciting a newly discovered property of an old alloy did not satisfy section 102 because the alloy itself was not new. Titanium Metals Corp. of Am. v. Banner, 778 F.2d 775, 782, 227 USPQ 773, 778 (Fed. Cir. 1985) and In re Pearson, 494 F.2d 1399, 1403, 181 USPQ 641, 644 (CCPA 1974). Moreover, "[M]ere statement of a new use for an otherwise old or obvious composition cannot render a claim to the composition patentable." In re Zierden, 411 F.2d 1325, 1328, 162 USPQ 102, 104 (CCPA 1969). No provision has been made in the patent statutes for granting a patent upon an old product based solely upon discovery of a new use for such product. In re Benner, 174 F.2d 938, 942, 82 USPQ 49, 53 (CCPA 1949).

In sum, appellants have not provided any argument or evidence which distinguishes the pharmaceutical agent of the prior art from that claimed. The rejections for anticipation over Keplinger or Stuppner are affirmed.

35 U.S.C. § 103

Claims 1-3, 11, 44-46 and 52 stand rejected under 35 U.S.C. § 103 as obvious over Keplinger or Stuppner.

Claims 1-3 and 44-46

As indicated above, claims 1 and 44 are pharmaceutical composition claims and not method claims. Claim 1 has been found be anticipated by Keplinger or Stuppner. Anticipation being the epitome of obviousness, we also affirm the rejection of claim 1 under 35 U.S.C. § 103 as being obvious in view of Keplinger or Stuppner. See In re Fracalossi, 681 F.2d 792, 794, 215 USPQ 569, 571 (CCPA 1982). Claims 2, 3 and 44-46 fall with claim 1.

Claims 11 and 52

The examiner acknowledges that neither Keplinger or Stuppner teaches a composition containing a weight percentage of plant extract of 70-95%. Answer, page 6. This claim limitation is only present in claims 11 and 52. The examiner argues that the "amount of active ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been routine for an artisan of ordinary skill to determine the optimal amount of *U. tomentosa* to use in the composition in order to

achieve the desired results." Answer, page 6.

In In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955), a predecessor of our appellate reviewing court set out the rule that the discovery of an optimum value of a variable in a known process is normally obvious. Exceptions to this rule have been found in cases where the results of optimizing a variable, which was known to be result effective, were unexpectedly good. In re Waymouth, 499 F.2d 1273, 1276, 182 USPQ 290, 293 (CCPA 1974). Another exception is the case in which the parameter optimized was not recognized to be a result-effective variable. See In re Antonie, 559 F.2d 618, 619, 195 USPQ 6, 8 CCPA 1977). It was determined in In re Sebek, 465 F.2d 904, 907, 175 USPQ 93, 95 (CCPA 1972) that in "an area of technology shown to be highly unpredictable in process values, the discovery of optimum values not in any way suggested by the prior art is more likely to be unobvious than obvious within the meaning of § 103."

Appellants argue that "the Examiner has shown no basis upon which a person of ordinary skill could proceed with such an optimization..." Brief, page 15. We agree with appellants that the examiner has failed to establish a prima facie case of obviousness for claims 11 and 52.

Findings of fact and conclusions of law must be made in accordance with the Administrative Procedure Act, 5 U.S.C. 706 (A), (E) (1994). See Zurko v. Dickinson, 527 U.S. 150, 158, 119 S.Ct. 1816, 1821, 50 USPQ2d 1930, 1934 (1999). Findings of fact relied upon in making the obviousness rejection must be supported by substantial

evidence within the record. See In re Gartside, 203 F.3d 1305, 1315, 53 USPQ2d 1769, 1775 (Fed. Cir. 2000). Patent examiners, in relying on what they assert to be general knowledge to negate patentability on the ground of obviousness, must articulate that knowledge and place it on record, since examiners and the board are presumed to act from the viewpoint of person of ordinary skill in the art in finding relevant facts, the assessing significance of prior art, and making the ultimate determination of obviousness issue; failure to do so is not consistent with either effective administrative procedure or effective judicial review, and the board cannot rely on conclusory statements when dealing with particular combinations of prior art and specific claims, but must set forth the rationale on which it relies. In re Lee, 277 F.3d 1338, 1343-1344, 61 USPQ2d 1430, 1433-1434 (Fed. Cir. 2002).

The examiner has not provided evidence of knowledge in the art of a pharmaceutical agent which is an extract of Uncaria tomentosa, wherein the weight percentage of plant extract in the agent is in the range of from about 70% to about 95%, and thus we are constrained to find the examiner has not established a prima facie case of obviousness with respect to claims 11 and 52. The examiner has not explained what would have led the skilled artisan to make the composition having the specific range of weight percent of extract. The rejection of the claims is reversed.

CONCLUSION

The rejections of claims 1-10, 12, 13, 44-51, 53 and 54 under 35 U.S.C. § 102(b) as anticipated by Keplinger and claims 1-6, 9, 10, 12, 13, 44-47, 50, 51, 53 and 54 under 35 U.S.C. § 102(b) as anticipated by Stuppner are affirmed. The rejection of claims 1-3, and 44-46 under 35 U.S.C. § 103 as obvious over Keplinger or Stuppner is affirmed. The rejection of claims 5, 6, 9, 47 and 50 under 35 U.S.C. § 112, second paragraph, as indefinite, is affirmed. The rejection of claims 11 and 52 under 35 U.S.C. § 103 as obvious over Keplinger or Stuppner is reversed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED-IN PART

TONI R. SCHEINER
Administrative Patent Judge

DEMETRA J. MILLS
Administrative Patent Judge

LORA M. GREEN
Administrative Patent Judge

) APPEALS AND
) INTERFERENCES

Appeal No. 2003-0565
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